

COMPARISON OF THE EFFICACY & SAFETY OF CELBESTA[®] VS CELEBRES[®] IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background/Aims: Celecoxib, a selective cyclo-oxygenase (COX) II inhibitor, is being commonly using non-steroidal anti-inflammatory drugs (NSAIDs) to reduce the incidence of gastrointestinal (GI) complication in patients with rheumatoid arthritis (RA). CELBESTA[®] is generic medicine of CELEBRES[®], which is celecoxib. This study aimed to compare the efficacy and safety of CELBESTA[®] and CELEBRES[®] in patients with RA. **Methods:** This study was a multicenter, double-blinded, double-dummy, active-controlled, randomized, parallel-group, non-inferiority clinical trial. After washout periods, 119 eligible subjects were randomized to receive either CELBESTA[®] 200mg or CELEBRES[®] 200mg twice a day for 6 weeks. The primary endpoint was a change from baseline after 6 weeks treatment in patient assessment of pain intensity using a 100 mm visual analog scale (VAS). The secondary endpoint was a change from baseline after 6 weeks treatment of disease activity score in 28 joints (DAS28-ESR, ESR=erythrocyte sedimentation rate) and safety profiles. **Results:** 133 subjects were screened from 10 nationwide institutions in Republic of Korea, and 119 subjects were randomized to each group ($n=61$ for CELBESTA[®] group, $n=58$ for CELEBRES[®] group). CELBESTA[®] and CELEBRES[®] both groups showed statistically significant reductions in VAS assessment after 6 weeks treatments compared with baselines (all $p<0.0001$), and CELBESTA[®] was not inferior to CELEBRES[®] as the upper limit of 95% 2-sided confidence interval (CI) for the difference between two groups (difference in LS means -8.68mm; 95% 2-sided CI -16.59mm to -0.77mm) was less than the non-inferiority margin (10mm). The secondary endpoint, the change from baseline after 6 weeks treatment of DAS28-ESR, didn't show statistically significant difference between the two groups ($p=0.0946$)(Figure 1), and no significant differences were found in 9 gastrointestinal complications and glomerular filtration rate. **Conclusions:** This study shows that CELBESTA[®] was not inferior to CELEBRES[®] in regard to pain relief effectiveness in patients with RA and also shows that the tolerability and safety profiles were good with similar levels between the two groups.

